Traditional 510(k)
SASMAR, Inc.

510(K) SUMMARY

ADMINISTRATIVE

510(k)	K131084
Submitter	SASMAR, INC. 155 North Wacker Drive Suite 4250 Chicago, IL 60606 USA
Contact	John-Michael Mancini Chief Executive Officer Tel: (773) 942 0030 Fax: (773) 337 9148
Manufacturer	SASMAR SPRL 40-42 rue de l'Association 1000 Brussels Belgium Tel +32 2 880 8220 Fax +32 2 880 8221
Date Prepared	September 9, 2013

SEP 13 2013

DEVICE NAMES AND CLASSIFICATIONS

Trade / Proprietary Names	SASMAR® ORIGINAL SASMAR® CLASSIC
Common Name	Personal Lubricant
Classification	Condom Class II (21 CFR 884.5300) NUC

SUBSTANTIAL EQUIVALENCE

For SASMAR® CLASSIC:

- Lifestyles® Natural Personal Lubricant (K122054)

For SASMAR® ORIGINAL:

- K-Y® Brand Intrigue (K062796)

DEVICE DESCRIPTION

SASMAR® ORIGINAL is a non-sterile silicone based personal lubricant for penile and/or vaginal application intended to facilitate condom use, provide additional moisture to relieve vaginal dryness and enhance pleasure during sexual intimacy. The device may be used as a massage lotion and is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

This product is provided in a plastic pump dispenser or a foil laminate sachet and is available over-the-counter.

SASMAR® CLASSIC is a non-sterile water-based personal lubricant for penile and/or vaginal application intended to facilitate condom use, provide additional moisture to relieve vaginal dryness and enhance pleasure during sexual intimacy. The formula is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

The device is available in the following variant personal lubricant formulas:
SASMAR® Warming, SASMAR® Vanilla, SASMAR® Melon, SASMAR® Cherry, SASMAR® Strawberry or SASMAR® Pina Colada.

This product is provided in a plastic pump dispenser, a plastic tube with flip-top closure or a foil laminate sachet and is available over-the-counter.

INTENDED USE

SASMAR® ORIGINAL is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms

SASMAR® CLASSIC is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

TECHNOLOGICAL CHARACTERISTICS

SASMAR® ORIGINAL and SASMAR® CLASSIC are proprietary formulations. The devices have similar ingredients, similar composition and intended use as other lubricants currently sold on the U.S market and are substantially equivalent to the predicate device. Any minor differences in technological characteristics between the predicate devices do not raise new issues of safety or efficacy. Testing per ASTM D7661 indicates that the lubricant formulations are compatible with condoms. As with the predicate, testing for cytotoxicity, vaginal irritation, sensitization and systemic toxicity in accordance with ISO 10993 indicated device biocompatibility. Bench testing indicated that the lubricant is has an appropriate viscosity, pH, osmolarity, specific gravity, appearance, color and odor for substantial equivalence to the predicates. USP testing for Total Aerobic Microbial Count, Total Yeast and Mold Count, absence of microbial pathogens and antimicrobial effectiveness indicated microbial quality. Long term, accelerated and real time aging tests for physical parameters and microbial characteristics indicate a 30 month shelf-life for the lubricants.

CONCLUSION

SASMAR® ORIGINAL and SASMAR® CLASSIC have the same intended use and basic technological characteristics as the predicate devices and are as safe and effective as their predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 13, 2013

SASMAR, Inc.
% John-Michael Mancini
Chief Executive Officer
155 North Wacker Drive, Suite 4250
Chicago, IL 60606

Re: K131084
Trade/Device Name: SASMAR® CLASSIC, SASMAR® ORIGINAL, SASMAR® VANILLA, SASMAR® WARMING, SASMAR® CHERRY, SASMAR® MELON, SASMAR® PINA COLADA, SASMAR® STRAWBERRY
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: July 29, 2013
Received: August 14, 2013

Dear John-Michael Mancini,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K131084

Device Name: **SASMAR® CLASSIC**

Indications for use: SASMAR® CLASSIC is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

INDICATIONS FOR USE

510(k) Number: K131084

Device Name: **SASMAR® ORIGINAL**

Indications for use: SASMAR® ORIGINAL is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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INDICATIONS FOR USE

510(k) Number: K131084

Device Name: **SASMAR® VANILLA**

Indications for use: SASMAR® VANILLA is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Prescription Use ____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Herbert P. Lerner -S

INDICATIONS FOR USE

510(k) Number: K131084

Device Name: **SASMAR® WARMING**

Indications for use: SASMAR® WARMING is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Herbert P. Lerner -S

INDICATIONS FOR USE

510(k) Number: K131084

Device Name: **SASMAR® CHERRY**

Indications for use: SASMAR® CHERRY is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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INDICATIONS FOR USE

510(k) Number: K131084

Device Name: **SASMAR® MELON**

Indications for use: SASMAR® MELON is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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INDICATIONS FOR USE

510(k) Number: K131084

Device Name: **SASMAR® PINA COLADA**

Indications for use: SASMAR® PINA COLADA is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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INDICATIONS FOR USE

510(k) Number: K131084

Device Name: **SASMAR® STRAWBERRY**

Indications for use: SASMAR® STRAWBERRY is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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